

[REDACTED]

From: [REDACTED]
Sent: 29 July 2008 09:35
To: [REDACTED]
Cc: [REDACTED]
Subject: Appeal - Final Appraisal Determination: Alendronate etidronate risedronate and strontium ranelate for the (FAD 1) primary and (FAD 2) secondary prevention of osteoporotic fragility fractures in post menopausal women
Importance: High

29 July 2008

NHS
**National Institute for
 Health and Clinical Excellence**

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Dear [REDACTED]

Final Appraisal Determination: Alendronate etidronate risedronate and strontium ranelate for the (FAD 1) primary and (FAD 2) secondary prevention of osteoporotic fragility fractures in post menopausal women

Thank you for lodging Servier Laboratories appeal against the above Final Appraisal Determinations.

Introduction

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are at least arguably within the permitted grounds of appeal ("valid"). The permitted grounds of appeal are:

- Ground 1: The Institute has failed to act fairly and in accordance with its published procedures as set out in the Institute's Guide to the Technology Appraisal Process.
- Ground 2: The Institute has prepared guidance which is perverse in the light of the evidence submitted.
- Ground 3: The Institute has exceeded its powers.

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am satisfied that your points contain the necessary information and arguably fall within any one of the grounds will your appeal be referred to the Appeal Panel.

You have the opportunity to comment on this letter in order to elaborate on or clarify any of the points raised before I make my final decision as to whether each appeal point should be referred on to the Appeal Panel.

Initial View

I note that your appeal raises points considered at an appeal hearing against earlier FADs generated in these appraisals, as well as some wholly new points, and some points which are partly new and partly already considered.

As to the points already considered, (some of which as you note are subject to a judicial review) I note that you anticipate that

[REDACTED]

the appeal panel would feel bound to reject these points, having already done so once. I think that that is correct, at least in the absence of some relevant change of circumstance. I therefore am minded to conclude that these points (1,3,4,6,7,9, and 10 in your numbering) should not proceed.

As to the new points raised (5 and 8) I agree these are valid appeal points and should be considered by an appeal panel.

As to the points which are partly new and partly already considered, (2 and 11) strictly I would be minded to rule that only the new arguments should be considered. However I feel this may lead to a stilted presentation of the arguments at appeal and/or it may be that the new arguments to be presented will colour the panel's understanding of the old material. Therefore I propose that the whole of those two points should go forward, albeit that it is probable that the appeal panel will simply repeat its earlier findings in respect of some of the arguments being put.

As I am minded to rule that at least some of your appeal points are valid, I will pass your appeal to the Appeal Panel for consideration.

If you wish to make any further comment I would be grateful to receive this within fourteen days.

Yours sincerely

Sir Michael Rawlins
Chair
National Institute for Health and Clinical Excellence

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